

OMB 2020-0003  
Expires: XXXX  
Inert Ingredients

**Request for Substantiation From an Affected Business**

**By Certified U.S. Mail; Return Receipt Requested**

*[Name, title, and address of the [designated] representative of the affected business]*

RE: Confidential Business Information Determination

Dear [ADDRESSEE]:

The U.S. Environmental Protection Agency (“EPA”) Office of Pesticide Programs has received a request under the FOIA for certain records *[if submitted by the business whose information it is: that you submitted to the EPA] [if submitted by an entity other than the business whose information it is: in EPA’s possession]* pertaining to *[a detailed description of the information or specific list of documents that is/are the subject of the advance or final confidentiality determination]*. *[If information has been claimed as CBI: You have claimed (all or part) of this information as confidential business information (“CBI”).] [If no claim has been made: In accordance with applicable EPA regulations, 40 C.F.R. Part 2, Subpart B, the EPA has determined that you might be expected to assert a claim that some or all of [if submitted by the business whose information it is: the information you submitted to the EPA] [if submitted by an entity other than the business whose information it is: this information in EPA’s possession] is confidential business information (“CBI”).]* Under the EPA regulations at 40 C.F.R. Part 2, Subpart B, the FOIA request has been initially denied to afford you an opportunity to provide comments to *[If no claim has been made: claim this information as CBI and]* substantiate your claim(s) as described below.

The purpose of this letter is to notify you that the EPA Office of General Counsel will be making a(n) *[advance or final]* confidentiality determination concerning the information you have claimed as CBI. If you feel that some or all of the information is entitled to confidential treatment, you must make the showings below with specific reference to those portions of the information you consider confidential.

Please be specific by page (including Bates Stamp, if applicable), paragraph, and sentence when identifying and substantiating the information subject to your claim. Where your claim, as originally made or as modified by your response to this letter, does not include all information on a page, please attach a copy of each such page with brackets around the text that

you claim to be CBI. Please note that if a page, document, group, or class of documents claimed by you to be CBI contains a significant amount of information which the Office of General Counsel determines is not CBI, your CBI claim regarding that page, document, group, or class of documents may be denied. Any information not specifically identified as subject to a confidentiality claim and substantiated as such in your response to this letter may be disclosed to the requester without further notice to you.

1. For what period of time do you request that the information be maintained as confidential? If the occurrence of a specific event will eliminate the need for confidentiality, please specify that event.
2. Information submitted to EPA becomes stale over time. Why should the information you claim as confidential be protected for the time period specified in your answer to question #1?
3. What measures have you taken to protect the information claimed as confidential? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose the information further? If so, why should the information still be considered confidential?
4. Has any governmental body made a determination as to the confidentiality of the information? If so, please attach a copy of the determination.
5. Is the information contained in any publicly available material such as promotional publications, annual reports, articles, etc.? Is there any means by which a member of the public could obtain access to the information?
6. For each category of information claimed as confidential, discuss with specificity why release of the information is likely to cause substantial harm to your competitive position. Explain the nature of those harmful effects, why they should be viewed as substantial, and the causal relationship between disclosure and such harmful effects. How could your competitors make use of this information to your detriment?
7. Do you assert that the information is "voluntarily submitted" as defined at 40 C.F.R. § 2.201(i)? If so, explain why and how disclosure would tend to lessen EPA's ability to obtain similar information in the future.
8. Any other issue you deem relevant.

Please note that you bear the burden of substantiating your confidentiality and trade secret claim(s) pursuant to 40 CFR § 2.208(e). Generalize or conclusory allegations will be given little or no weight in EPA's determination on the confidentiality of information you claim to be CBI.

If you wish to claim any information that you provide in your response to this letter to itself be confidential, you must mark the response "**CONFIDENTIAL**" or with a similar

designation, and must bracket all text in the response that you so claim. Information so designated will be disclosed by the EPA only to the extent allowed by, and by means of the procedures set forth in, 40 C.F.R. Part 2, Subpart B. If you fail to claim the information provided in your response as confidential, it may be made available to the public without further notice to you.

Your reply can be mailed to the following address:

Or your reply can be delivered to the following address:

Your comments must be postmarked or hand-delivered by the 15th working day after your receipt of this letter. If you intend to submit timely comments, please notify by phone at [TELEPHONE NUMBER], by email at or by mail at the address above. Failure to submit timely comments will be regarded as a waiver of your confidentiality claim and EPA will release the information. You may request an extension of the 15-day deadline. Except in extraordinary circumstances, no extension will be granted without the permission of the requestor.

Should you have any questions in this matter, please contact [CONTACT NAME].

Sincerely,

Enclosures

LETTER D: FIFRA; Non-FOIA

OMB 2020-0003

Expires

**Request for Substantiation From an Affected Business**

**By Certified U.S. Mail; Return Receipt Requested**

*[Name, title, and address of the [designated] representative of the affected business]*

Re: Freedom of Information Act Request [INSERT NUMBER]

Dear [INSERT NAME]:

The U.S. Environmental Protection Agency (“EPA”) Office of Pesticide Programs is seeking to determine the entitlement to confidentiality of *[description of the information that is the subject of the advance or final confidentiality determination]* *[if submitted by the business whose information it is: that you submitted to the EPA]* *[if submitted by an entity other than the business whose information it is: in EPA’s possession.]* *[If information has been claimed as CBI: You have claimed (all or part) of this information as confidential business information (“CBI”).]* *[If no claim has been made: In accordance with applicable EPA regulations, 40 C.F.R. Part 2, Subpart B, the EPA has determined that you might be expected to assert a claim that some or all of [if submitted by the business whose information it is: the information you submitted to the EPA] [if submitted by an entity other than the business whose information it is: this information in EPA’s possession] is confidential business information (“CBI”).]*

The purpose of this letter is to notify you that the EPA Office of General Counsel will be making a(n) *[advance or final]* confidentiality determination concerning the information you have claimed as CBI. If you feel that some or all of the information is entitled to confidential treatment, you must make the showings below with specific reference to those portions of the information you consider confidential.

Please be specific by page (including Bates Stamp, if applicable), paragraph, and sentence when identifying and substantiating the information subject to your claim. Where your claim, as originally made or as modified by your response to this letter, does not include all information on a page, please attach a copy of each such page with brackets around the text that you claim to be CBI. Please note that if a page, document, group, or class of documents claimed by you to be CBI contains a significant amount of information which the Office of General Counsel determines is not CBI, your CBI claim regarding that page, document, group, or class of documents may be denied. Any information not specifically identified as subject to a confidentiality claim and substantiated as such in your response to this letter may be disclosed to the requester without further notice to you.

Questions 1-7 must be answered with respect to any confidentiality claims pertaining to the enclosed product chemistry information.

1. What value can your competitors derive from knowing the identity, percent by weight, certified limits, or parent process of each impurity? Is this impurity unique to your manufacturing process? Why would your competitors find this impurity preferable over whatever impurity results from their equivalent process?
2. Does published analytical methodology exist that could identify and quantify this impurity? If so, why do you believe that your competitors have not already performed such analysis?
3. What value can your competitors derive from knowing the description of materials used to produce the product, the description of the production process, or the preliminary production analysis? Why would your competitors find these processes preferable over their equivalent processes?

Questions 4-7 must be answered with respect to any confidentiality claims pertaining to the inert ingredients. Each question must be answered separately with respect to each inert ingredient:

4. What is the value that this inert ingredient brings to the product formulation? What characteristics of this ingredient are unique such that competitors might prefer it over whatever ingredients perform the equivalent function in their formulations? Is the use of this ingredient limited to your product, or does it have broader applications?
5. Why is it unlikely that your competitors have not already discovered the value of this ingredient? Are you aware of the use of this ingredient as an inert by your competitors?
6. To your knowledge, has the use of this inert ingredient in a pesticide been disclosed in a patent? If so, how would disclosure of the identity of the ingredient assist your competitors beyond what is already available through a patent?
7. Can the identity of this inert ingredient be determined by product sample analysis? If so, why do you believe that your competitors have not already performed such analysis?

Question 8 must be answered with respect to any confidentiality claims pertaining to the enclosed records:

8. For each category of information claimed as confidential, discuss with specificity why release of the information is likely to cause substantial harm to your competitive position. Explain the nature of those harmful effects, why they should be viewed as substantial, and the causal relationship between disclosure and such harmful effects. How could your competitors make use of this information to your detriment?

Questions 9 through 15 must be answered for each type of information that you claimed as confidential:

9. For what period of time do you request that the information be maintained as confidential? If the occurrence of a specific event will eliminate the need for confidentiality, please specify that event.
10. Information submitted to EPA becomes stale over time. Why should the information you claim as confidential be protected for the time period specified in your answer to question number 9?
11. What measures have you taken to protect the information? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose it further? If so, why should it still be considered confidential?
12. Has any governmental body made a determination as to the confidentiality of the information? If so, please attach a copy of the determination.
13. Is the presence of this information disclosed in any publicly available material such as Material Safety Data Sheets, promotional publications, annual reports, articles, etc.? Is there any means by which a member of the public could obtain access to the information?
14. Do you assert that the information is "voluntarily submitted" as defined at 40 CFR § 2.201(i)? If so, explain why, and how disclosure would tend to lessen EPA's ability to obtain similar information in the future.
15. Any other issue you deem relevant.

Please note that you bear the burden of substantiating your confidentiality and trade secret claim(s) pursuant to 40 CFR § 2.208(e). Generalize or conclusory allegations will be given little or no weight in EPA's determination on the confidentiality of information you claim to be CBI.

If you wish to claim any information that you provide in your response to this letter to itself be confidential, you must mark the response "**CONFIDENTIAL**" or with a similar designation, and must bracket all text in the response that you so claim. Information so designated will be disclosed by the EPA only to the extent allowed by, and by means of the procedures set forth in, 40 C.F.R. Part 2, Subpart B. If you fail to claim the information provided in your response as confidential, it may be made available to the public without further notice to you.

Be advised that information described by Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") section 10(d)(1)(A), (B), and (C) is not automatically entitled to confidential treatment. Disclosure of such information would only be prohibited, by FIFRA section (b), if the information is eligible for confidential treatment as described by 40 CFR 2.208.

Your reply can be mailed to the following address:

Or your reply can be delivered to my attention at the following address:

Your comments must be postmarked or hand-delivered by the 15th working day after your receipt of this letter. If you intend to submit timely comments, please notify by phone: [TELEPHONE], by email: [EMAIL ADDRESS], or by mail at the address above. Failure to submit timely comments will be regarded as a waiver of your confidentiality claim and EPA will release the information. You may request an extension of the 15-day deadline. Except in extraordinary circumstances, no extension will be granted without the permission of the requester.

Should you have any questions in this matter, please contact: [CONTACT PERSON].

Sincerely,

[SIGNATORY AND TITLE]

Enclosures

**LETTER E: TSCA**

OMB 2020-0003  
Approval expires

**By Certified U.S. Mail; Return Receipt Requested**

**MAY CONTAIN CONFIDENTIAL BUSINESS INFORMATION**

*[Technical Contact Name, title, Company, and Address]*

Re: Notice of Review and Request for Substantiation of Confidential Business Information Claim(s)

Document Type:

Document Identifying Number:

Date of Submission:

Type of claim(s) to be reviewed:     ☐ specific chemical identity  
   ☐ all other CBI claims

Dear *[Addressee]*:

Under the Toxic Substance Control Act (TSCA) most confidential business information (CBI) claims for chemical identity and at least 25% of other CBI claims are subject to a review and final determination. TSCA section 14(g). 15 U.S.C. § 2613(g).

This letter is to notify you that the U.S. Environmental Protection Agency (EPA) Office of General Counsel will be making a final confidentiality determination concerning information you have claimed as CBI, as identified above. All non-exempt CBI claims must be substantiated.

If you feel that some or all of the information checked above is entitled to confidential treatment, you must substantiate as described below with specific reference to those portions of the information you consider confidential.

Note that TSCA section 14(c)(2) generally exempts certain information types from the requirement to substantiate. 15 U.S.C. § 2613(c)(2). *See* EPA webpage [INSERT WEBPAGE] for more guidance on information exempt from substantiation. To the extent that you believe the information that you have claimed as CBI is one of these exempt information types, you may make this assertion in your response by identifying the specific section 14(c)(2) exemption, in



lieu of substantiating the CBI claim for that information. If the Agency disagrees with this assertion, you may be asked to provide additional information to support your claim.

### **Substantiating a CBI Claim.**

There are two different sets of substantiation questions for CBI claims: (I) questions for all CBI claims in the submission; and (II) questions for chemical identity CBI claims. Please use the appropriate question set. In some instances, your TSCA submission may contain both types of CBI claims or a CBI claim may require completing both sets of substantiation questions. For example, if you assert a CBI claim to protect a chemical substance's identity, then you must answer both question sets. EPA has identified the appropriate question set(s) via the checkboxes at the top of this letter. In some instances, for example TSCA section 8(a) Chemical Data Reporting (CDR) Rule submissions, you may have already provided up-front substantiations for some of the CBI claims. If you have already substantiated your CBI claim at the time of submission, please refer to or preferably physically attach your substantiation to your response to this letter.

Note also that the providing of incorrect information in this substantiation request may be a failure to comply with TSCA, specifically 15 U.S.C. § 2614.

### **I. REQUIRED FOR ALL CBI CLAIMS.**

**If you are asserting ANY information in the submission as CBI, please answer the following questions.**

In supporting your CBI claim(s), please be specific by page, paragraph, sentence, or by data element when identifying and substantiating the information subject to your claim. Where your claim, as originally made or as modified by your response to this letter, does not include all information on a page, please attach a copy of each such page with brackets around the text that you claim to be CBI.

In some cases, it may be appropriate to group the information into a class of information rather than responding to each item claimed as CBI. See EPA webpage [INSERT WEBPAGE] for suggested approaches to providing substantiations of materials grouped. For any information that is not specifically identified as subject to a confidentiality claim and substantiated as such in your response to this letter, it shall be determined that you have waived your CBI claim, pursuant to 40 C.F.R. § 2.205(d).

For each item or class of information that you continue to claim as CBI, please answer the following questions, giving as much detail as possible. Your substantiation response to these questions will be used by the EPA to determine whether the information has been shown to be entitled to confidential treatment:

- A. Do you believe that any of the information claimed as CBI is exempt from substantiation pursuant to TSCA section 14(c)(2)<sup>1</sup>? Yes/No.

If you answered yes, please identify the information, provide the specific exemption and answer no further questions related to that information.

If you answered no, please respond to the questions below.

- B. Will disclosure of the information likely result in substantial harm to your business competitive position? Yes/No.

If you answered yes, please describe with specificity the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public. In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitor's access to your customers.

- C. To the extent you have disclosed information to others (both internally and externally), what precautions has your business taken? Please identify any measures or internal controls your business has taken to protect the information claimed as confidential.

1. Non-disclosure agreement required prior to access. Yes/No
2. Access is limited to individuals with a need-to-know. Yes/No
3. Information is physically secured (e.g. locked in room or cabinet) or electronically secured (encrypted, password protected, etc.). Yes/No
4. Other internal control measure(s). If so, please explain.

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<sup>1</sup> TSCA Section 14(c)(2) states:

**(2) Information generally not subject to substantiation requirements**

Subject to subsection (f), the following information shall not be subject to substantiation requirements under paragraph (3):

(A) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

(B) Marketing and sales information.

(C) Information identifying a supplier or customer.

(D) In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents.

(E) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article.

(F) Specific production or import volumes of the manufacturer or processor.

(G) Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify the specific chemical substance, if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under section 2604 of this title.

- D. Does the information claimed as confidential appear in any public documents, including (but not limited to) safety data sheet, advertising or promotional material, professional or trade publication, or any other media or publications available to the general public? Yes/No.

If you answered yes, please explain why the information should nonetheless be treated as confidential.

- E. Does the information claimed to be CBI contain (a) trade secret(s)<sup>2</sup> ? Yes/No

If yes, please explain the reason for your belief. Please attach copies of those pages containing such information with brackets around the text that you claim to be (a) trade secret(s).

- F. If you assert a claim of confidentiality that is less than 10 years (see TSCA section 14(e)(1)(B)), then please indicate the number of years (between 1-10 years) or specific date of which the claim is withdrawn.<sup>3</sup>

- G. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? Yes/No.

If yes, please explain the outcome of that determination and provide EPA with a copy of the previous confidentiality determination or any information that will assist the Agency in identifying the prior determination.

## II. REQUIRED FOR ONLY CHEMICAL IDENTITY CBI CLAIMS.

**If you are claiming a specific chemical identity as CBI, please answer the additional following questions.** If you are not substantiating a chemical identity CBI claim, then you do not need to respond to the questions below.

- A. Is the chemical substance on the confidential portion of the TSCA Inventory? Yes/No.
- B. Commerce:
1. Has the chemical substance (or mixture) been offered for commercial distribution? Yes/No.
  2. Is the chemical substance known to be in U.S. commerce? Yes/No.

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<sup>2</sup> “Trade secret” is defined as “a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort.” Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983).

<sup>3</sup> Information with withdrawn CBI claims will be made available to the public without further notice.

If you answered yes, please explain why the information should nonetheless be treated as confidential.

C. Disclosure of the specific chemical name would release:

1. Confidential process information. Yes/No.
2. Confidential portion of a mixture information. Yes/No.

If you answered yes to either question, please explain.

### **Asserting a CBI claim in your substantiation response.**

Businesses may claim their substantiation response as CBI. Information claimed as confidential should be clearly marked by bracketing, circling, or underlining. All pages containing such information must also be stamped "CONFIDENTIAL BUSINESS INFORMATION" or with similar designation in order to assert a confidentiality claim. Care should be taken to ensure that these markings do not obscure the text.

If you claim your substantiation response as CBI, you must include the following statement in the submission.

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.

I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

- (i) My company has taken reasonable measures to protect the confidentiality of the information;
- (ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
- (iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and
- (iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

### **Timely Responses and Postal Requirements**

Your substantiation response must be postmarked or hand delivered to this office **by the 15th working day after your receipt of this letter.** While it is anticipated that there will be a means

for sending these to the Agency electronically in the future, at this point substantiations should be sent via US Mail or courier.

**Filings should be directed to the below address.**

TSCA Confidential Business Information Center (7407M)  
WJC East; Room 6428; Attn: TSCA CBI Substantiations  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460-0001

**Courier Deliveries:**

U.S. EPA  
Office of Pollution Prevention and Toxics  
Confidential Business Information Center (CBIC)  
Attn: TSCA CBI Substantiations  
1201 Constitution Avenue, NW  
WJC East; Room 6428  
Washington, DC 20004-3302  
(202) 564-8930

You may seek an extension of time to submit your substantiation response to this office, but the request must be made before the end of the 15-day period. Requests for an extension may be directed to Ms. Quoc Nguyen, Office of General Counsel, [Nguyen.Quoc@epa.gov](mailto:Nguyen.Quoc@epa.gov).

**Failure to timely submit your substantiation response will be regarded as a waiver of your confidentiality claim or claims, and the EPA may release the information.**

Should you have any questions concerning this matter, please contact Mr. Scott Sherlock, (202) 564-8257 and [Sherlock.Scott@epa.gov](mailto:Sherlock.Scott@epa.gov); or Ms. Jessica Barkas, (202) 250-8880 and [Barkas.Jessica@epa.gov](mailto:Barkas.Jessica@epa.gov).

Sincerely,

[Signature and Title; Office Name and Address]

**SAMPLE LETTER A: Generic Substantiation, FOIA**

Approved OMB 2020-0003  
Approval expires XXXX

**Request for Substantiation In Response to a  
Request Under the Freedom Of Information Act**

**By Certified U.S. Mail; Return Receipt Requested**

*(Name, title, and address of the [designated] representative of the affected business)*

Re: Freedom of Information Act (FOIA) Request [INSERT FOIA #]

Dear [Addressee]:

The U.S. Environmental Protection Agency (“EPA” or “Agency”) has received a request under the FOIA for certain records *[if submitted by the business whose information it is: that you submitted to the EPA] [if submitted by an entity other than the business whose information it is: in EPA’s possession]* pertaining to *[a detailed description of the information or specific list of documents that is/are the subject of the advance or final confidentiality determination]*. *[If information has been claimed as CBI: You have claimed (all or part) of this information as confidential business information (“CBI”).] [If no claim has been made: In accordance with applicable EPA regulations, 40 C.F.R. Part 2, Subpart B, the EPA has determined that you might be expected to assert a claim that some or all of [if submitted by the business whose information it is: the information you submitted to the EPA] [if submitted by an entity other than the business whose information it is: this information in EPA’s possession] is confidential business information (“CBI”).]* Under the EPA regulations at 40 C.F.R. Part 2, Subpart B, the FOIA request has been initially denied to afford you an opportunity to provide comments to *[If no claim has been made: claim this information as CBI and]* substantiate your claim(s) as described below.

The purpose of this letter is to notify you that the EPA (*appropriate legal office*) will be making a(n) (*advance or final*) confidentiality determination concerning the information you have claimed as CBI. If you feel that some or all of the information is entitled to confidential treatment, you must make the showings below with specific reference to those portions of the information you consider confidential.

Please be specific by page (including Bates Stamp, if applicable), paragraph, and sentence when identifying and substantiating the information subject to your claim. Where your claim, as originally made or as modified by your response to this letter, does not include all information on a page, please attach a copy of each such page with brackets around the text that

you claim to be CBI. Please note that if a page, document, group, or class of documents claimed by you to be CBI contains a significant amount of information which (*appropriate legal office*) determines is not CBI, your CBI claim regarding that page, document, group, or class of documents may be denied. Any information not specifically identified as subject to a confidentiality claim and substantiated as such in your response to this letter may be disclosed to the requester without further notice to you.

For each item or class of information that you continue to claim as CBI, please answer the following questions, giving as much detail as possible. Your comments in response to these questions will be used by the EPA to determine whether the information has been shown to be entitled to confidential treatment:

1. For what period of time do you request that the information be maintained as confidential, e.g., until a certain date, until the occurrence of a specified event, or permanently? If the occurrence of a specific event will eliminate the need for confidentiality, please specify that event.
2. Information submitted to the EPA becomes stale over time. Why should the information you claim as confidential be protected for the time period specified in your answer to question #1?
3. What measures have you taken to protect the information claimed as confidential? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose the information further? If so, why should the information be considered confidential?
4. Is the information contained in any publicly available material such as the Internet, publicly available databases, promotional publications, annual reports, or articles? If so, specify which.
5. Is there any means by which a member of the public could obtain access to the information? Is the information of a kind that you would customarily not release to the public?
6. Has any governmental body made a determination as to the confidentiality of the information? If so, please attach a copy of the determination.
7. For each item or category of information claimed as confidential, *explain with specificity* why release of the information is likely to cause substantial harm to your competitive position. Explain the specific nature of those harmful effects, why they should be viewed as substantial, and the causal relationship between disclosure and such harmful effects. How could your competitors make use of this information to your detriment?
8. Do you assert that the information is submitted on a voluntary or a mandatory basis? Please explain the reason for your assertion. If you assert that the information is

voluntarily submitted information, please explain whether the information is the kind that would customarily not be released to the public.

9. Whether you assert the information as voluntary or involuntary, please address why disclosure of the information would tend to lessen the availability to the EPA of similar information in the future.
10. If you believe any information to be (a) trade secret (s), please so state and explain the reason for your belief. Please attach copies of those pages containing such information with brackets around the text that you claim to be (a) trade secret (s).
11. Explain any other issue you deem relevant (including, if pertinent, reasons why you believe that the information you claim to be CBI is not emission data or effluent data).

[*For contract-related CBI:* Enclosed is the EPA Class Determination 1-95 entitled, *Confidentiality of Certain Business Information Submitted by Contractors and Prospective Contractors*, which addresses the treatment of different types of information related to contracts. You may consider reviewing Class Determination 1-95 as you develop your response.]

[*If applicable to another EPA class determination:* Enclosed is the EPA Class Determination [class determination number] entitled, [name of the class determination], which addresses the treatment of [description of class determination]. You may consider reviewing Class Determination [#] as you develop your response.]

Please note that *you bear the burden of substantiating your confidentiality and trade secret claim(s)*. Generalized or conclusory statements will be given little or no weight in EPA's determination on the confidentiality of the information you claim to be CBI.

Your comments must be postmarked or hand delivered to this office, or emailed to [email address], by the 15th working day after your receipt of this letter. You may seek an extension of time to submit your comments to this office, but the request must be made before the end of the 15-day period. Except in extraordinary circumstances, no extension will be approved without the consent of the FOIA requester. Failure to submit your comments within that time will be regarded as a waiver of your confidentiality claim or claims, and the EPA may release the information.

If you wish to claim any information that you provide in your response to this letter to itself be confidential, you must mark the response “**CONFIDENTIAL**” or with a similar designation, and must bracket all text in the response that you so claim. Information so designated will be disclosed by the EPA only to the extent allowed by, and by means of the procedures set forth in, 40 C.F.R. Part 2, Subpart B. If you fail to claim the information provided in your response as confidential, it may be made available to the public without further notice to you.



Should you have any questions concerning this matter, please call me at [*telephone number*].

Sincerely,

[Signature and Title ; Office Name and Address]

[Enclosure]

**SAMPLE LETTER B: Generic Substantiation, Non-FOIA**

Approved OMB 2020-0003

Approval expires xxxx

**Request for Substantiation From an Affected Business**

**By Certified U.S. Mail; Return Receipt Requested**

*[Name, title, and address of the [designated] representative of the affected business]*

Re: \_\_\_\_\_

Dear *[Addressee]*:

The U.S. Environmental Protection Agency (“EPA” or “Agency”) is seeking to determine the entitlement to confidentiality of *[description of the information that is the subject of the advance or final confidentiality determination]* *[if submitted by the business whose information it is: that you submitted to the EPA]* *[if submitted by an entity other than the business whose information it is: in EPA’s possession.]* *[If information has been claimed as CBI: You have claimed (all or part) of this information as confidential business information (“CBI”).]* *[If no claim has been made: In accordance with applicable EPA regulations, 40 C.F.R. Part 2, Subpart B, the EPA has determined that you might be expected to assert a claim that some or all of [if submitted by the business whose information it is: the information you submitted to the EPA] [if submitted by an entity other than the business whose information it is: this information in EPA’s possession] is confidential business information (“CBI”).]*

The purpose of this letter is to notify you that the EPA *[appropriate legal office]* will be making a(n) *[advance or final]* confidentiality determination concerning the information you have claimed as CBI. If you feel that some or all of the information is entitled to confidential treatment, you must make the showings below with specific reference to those portions of the information you consider confidential.

Please be specific by page (including Bates Stamp, if applicable), paragraph, and sentence when identifying and substantiating the information subject to your claim. Where your claim, as originally made or as modified by your response to this letter, does not include all information on a page, please attach a copy of each such page with brackets around the text that you claim to be CBI. Please note that if a page, document, group or class of documents claimed by you to be CBI contains a significant amount of information which our *[appropriate legal office]* determines is not CBI, your CBI claim regarding that page, document, group, or class of documents may be denied. Any information not specifically identified as subject to a confidentiality claim and substantiated as such in your response to this letter may be disclosed without further notice to you.

For each item or class of information that you continue to claim as CBI, please answer the following questions, giving as much detail as possible. Your comments in response to these questions will be used by the EPA to determine whether the information has been shown to be entitled to confidential treatment:

1. For what period of time do you request that the information be maintained as confidential, e.g., until a certain date, until the occurrence of a specified event, or permanently? If the occurrence of a specific event will eliminate the need for confidentiality, please specify that event.
2. Information submitted to the EPA becomes stale over time. Why should the information you claim as confidential be protected for the time period specified in your answer to question #1?
3. What measures have you taken to protect the information claimed as confidential? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose the information further? If so, why should the information be considered confidential?
4. Is the information contained in any publicly available material such as the Internet, publicly available databases, promotional publications, annual reports, or articles? If so, specify which.
5. Is there any means by which a member of the public could obtain access to the information? Is the information of a kind that you would customarily not release to the public?
6. Has any governmental body made a determination as to the confidentiality of the information? If so, please attach a copy of the determination.
7. For each item or category of information claimed as confidential, *explain with specificity* why release of the information is likely to cause substantial harm to your competitive position. Explain the specific nature of those harmful effects, why they should be viewed as substantial, and the causal relationship between disclosure and such harmful effects. How could your competitors make use of this information to your detriment?
8. Do you assert that the information is submitted on a voluntary or a mandatory basis? Please explain the reason for your assertion. If you assert that the information is voluntarily submitted information, please explain whether the information is the kind that would customarily not be released to the public.
9. Whether you assert the information as voluntary or involuntary, please address why disclosure of the information would tend to lessen the availability to the EPA of similar information in the future.

10. If you believe any information to be (a) trade secret(s), please so state and explain the reason for your belief. Please attach copies of those pages containing such information with brackets around the text that you claim to be (a) trade secret(s).
11. Explain any other issue you deem relevant (including, if pertinent, reasons why you believe that the information you claim to be CBI is not emission data or effluent data).

[*For contract-related CBI:* Enclosed is the EPA Class Determination 1-95 entitled, *Confidentiality of Certain Business Information Submitted by Contractors and Prospective Contractors*, which addresses the treatment of different types of information related to contracts. You may consider reviewing Class Determination 1-95 as you develop your response.]

[*If applicable to another EPA class determination:* Enclosed is the EPA Class Determination [class determination number] entitled, [name of the class determination], which addresses the treatment of [description of class determination]. You may consider reviewing Class Determination [#] as you develop your response.]

Please note that *you bear the burden of substantiating your confidentiality and trade secret claim(s)*. Generalized or conclusory statements will be given little or no weight in EPA's determination on the confidentiality of the information you claim to be CBI.

Your comments must be postmarked or hand delivered to this office, or emailed to [email address], by the 15th working day after your receipt of this letter. You may seek an extension of time to submit your comments to this office, but the request must be made before the end of the 15-day period. Except in extraordinary circumstances, no extension will be approved. Failure to submit your comments within that time will be regarded as a waiver of your confidentiality claim or claims, and the EPA may release the information.

If you wish to claim any information that you provide in your response to this letter to itself be confidential, you must mark the response "**CONFIDENTIAL**" or with a similar designation, and must bracket all text in the response that you so claim. Information so designated will be disclosed by the EPA only to the extent allowed by, and by means of the procedures set forth in, 40 C.F.R. Part 2, Subpart B. If you fail to claim the information provided in your response as confidential, it may be made available to the public without further notice to you.

Should you have any questions concerning this matter, please call me at [telephone number].

Sincerely,

[Signature and Title ; Office Name and Address]

[Enclosure]

OMB 2020-0003  
Expires: XXXX  
Inert Ingredients

**Request for Substantiation From an Affected Business**

**By Certified U.S. Mail; Return Receipt Requested**

*[Name, title, and address of the [designated] representative of the affected business]*

RE: Confidential Business Information Determination

Dear [ADDRESSEE]:

The U.S. Environmental Protection Agency (“EPA”) Office of Pesticide Programs has received a request under the FOIA for certain records *[if submitted by the business whose information it is: that you submitted to the EPA] [if submitted by an entity other than the business whose information it is: in EPA’s possession]* pertaining to *[a detailed description of the information or specific list of documents that is/are the subject of the advance or final confidentiality determination]*. *[If information has been claimed as CBI: You have claimed (all or part) of this information as confidential business information (“CBI”).] [If no claim has been made: In accordance with applicable EPA regulations, 40 C.F.R. Part 2, Subpart B, the EPA has determined that you might be expected to assert a claim that some or all of [if submitted by the business whose information it is: the information you submitted to the EPA] [if submitted by an entity other than the business whose information it is: this information in EPA’s possession] is confidential business information (“CBI”).]* Under the EPA regulations at 40 C.F.R. Part 2, Subpart B, the FOIA request has been initially denied to afford you an opportunity to provide comments to *[If no claim has been made: claim this information as CBI and]* substantiate your claim(s) as described below.

The purpose of this letter is to notify you that the EPA Office of General Counsel will be making a(n) *[advance or final]* confidentiality determination concerning the information you have claimed as CBI. If you feel that some or all of the information is entitled to confidential treatment, you must make the showings below with specific reference to those portions of the information you consider confidential.

Please be specific by page (including Bates Stamp, if applicable), paragraph, and sentence when identifying and substantiating the information subject to your claim. Where your claim, as originally made or as modified by your response to this letter, does not include all information on a page, please attach a copy of each such page with brackets around the text that

you claim to be CBI. Please note that if a page, document, group, or class of documents claimed by you to be CBI contains a significant amount of information which the Office of General Counsel determines is not CBI, your CBI claim regarding that page, document, group, or class of documents may be denied. Any information not specifically identified as subject to a confidentiality claim and substantiated as such in your response to this letter may be disclosed to the requester without further notice to you.

1. For what period of time do you request that the information be maintained as confidential? If the occurrence of a specific event will eliminate the need for confidentiality, please specify that event.
2. Information submitted to EPA becomes stale over time. Why should the information you claim as confidential be protected for the time period specified in your answer to question #1?
3. What measures have you taken to protect the information claimed as confidential? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose the information further? If so, why should the information still be considered confidential?
4. Has any governmental body made a determination as to the confidentiality of the information? If so, please attach a copy of the determination.
5. Is the information contained in any publicly available material such as promotional publications, annual reports, articles, etc.? Is there any means by which a member of the public could obtain access to the information?
6. For each category of information claimed as confidential, discuss with specificity why release of the information is likely to cause substantial harm to your competitive position. Explain the nature of those harmful effects, why they should be viewed as substantial, and the causal relationship between disclosure and such harmful effects. How could your competitors make use of this information to your detriment?
7. Do you assert that the information is "voluntarily submitted" as defined at 40 C.F.R. § 2.201(i)? If so, explain why and how disclosure would tend to lessen EPA's ability to obtain similar information in the future.
8. Any other issue you deem relevant.

Please note that you bear the burden of substantiating your confidentiality and trade secret claim(s) pursuant to 40 CFR § 2.208(e). Generalize or conclusory allegations will be given little or no weight in EPA's determination on the confidentiality of information you claim to be CBI.

If you wish to claim any information that you provide in your response to this letter to itself be confidential, you must mark the response "**CONFIDENTIAL**" or with a similar

designation, and must bracket all text in the response that you so claim. Information so designated will be disclosed by the EPA only to the extent allowed by, and by means of the procedures set forth in, 40 C.F.R. Part 2, Subpart B. If you fail to claim the information provided in your response as confidential, it may be made available to the public without further notice to you.

Your reply can be mailed to the following address:

Or your reply can be delivered to the following address:

Your comments must be postmarked or hand-delivered by the 15th working day after your receipt of this letter. If you intend to submit timely comments, please notify by phone at [TELEPHONE NUMBER], by email at or by mail at the address above. Failure to submit timely comments will be regarded as a waiver of your confidentiality claim and EPA will release the information. You may request an extension of the 15-day deadline. Except in extraordinary circumstances, no extension will be granted without the permission of the requestor.

Should you have any questions in this matter, please contact [CONTACT NAME].

Sincerely,

Enclosures

**SAMPLE LETTER D: FIFRA; Non-FOIA**

OMB 2020-0003

Expires

**Request for Substantiation From an Affected Business**

**By Certified U.S. Mail; Return Receipt Requested**

*[Name, title, and address of the [designated] representative of the affected business]*

Re: Freedom of Information Act Request [INSERT NUMBER]

Dear [INSERT NAME]:

The U.S. Environmental Protection Agency (“EPA”) Office of Pesticide Programs is seeking to determine the entitlement to confidentiality of *[description of the information that is the subject of the advance or final confidentiality determination]* *[if submitted by the business whose information it is: that you submitted to the EPA]* *[if submitted by an entity other than the business whose information it is: in EPA’s possession.]* *[If information has been claimed as CBI: You have claimed (all or part) of this information as confidential business information (“CBI”).]* *[If no claim has been made: In accordance with applicable EPA regulations, 40 C.F.R. Part 2, Subpart B, the EPA has determined that you might be expected to assert a claim that some or all of [if submitted by the business whose information it is: the information you submitted to the EPA] [if submitted by an entity other than the business whose information it is: this information in EPA’s possession] is confidential business information (“CBI”).]*

The purpose of this letter is to notify you that the EPA Office of General Counsel will be making a(n) *[advance or final]* confidentiality determination concerning the information you have claimed as CBI. If you feel that some or all of the information is entitled to confidential treatment, you must make the showings below with specific reference to those portions of the information you consider confidential.

Please be specific by page (including Bates Stamp, if applicable), paragraph, and sentence when identifying and substantiating the information subject to your claim. Where your claim, as originally made or as modified by your response to this letter, does not include all information on a page, please attach a copy of each such page with brackets around the text that you claim to be CBI. Please note that if a page, document, group, or class of documents claimed by you to be CBI contains a significant amount of information which the Office of General Counsel determines is not CBI, your CBI claim regarding that page, document, group, or class of documents may be denied. Any information not specifically identified as subject to a confidentiality claim and substantiated as such in your response to this letter may be disclosed to the requester without further notice to you.



Questions 1-7 must be answered with respect to any confidentiality claims pertaining to the enclosed product chemistry information.

1. What value can your competitors derive from knowing the identity, percent by weight, certified limits, or parent process of each impurity? Is this impurity unique to your manufacturing process? Why would your competitors find this impurity preferable over whatever impurity results from their equivalent process?
2. Does published analytical methodology exist that could identify and quantify this impurity? If so, why do you believe that your competitors have not already performed such analysis?
3. What value can your competitors derive from knowing the description of materials used to produce the product, the description of the production process, or the preliminary production analysis? Why would your competitors find these processes preferable over their equivalent processes?

Questions 4-7 must be answered with respect to any confidentiality claims pertaining to the inert ingredients. Each question must be answered separately with respect to each inert ingredient:

4. What is the value that this inert ingredient brings to the product formulation? What characteristics of this ingredient are unique such that competitors might prefer it over whatever ingredients perform the equivalent function in their formulations? Is the use of this ingredient limited to your product, or does it have broader applications?
5. Why is it unlikely that your competitors have not already discovered the value of this ingredient? Are you aware of the use of this ingredient as an inert by your competitors?
6. To your knowledge, has the use of this inert ingredient in a pesticide been disclosed in a patent? If so, how would disclosure of the identity of the ingredient assist your competitors beyond what is already available through a patent?
7. Can the identity of this inert ingredient be determined by product sample analysis? If so, why do you believe that your competitors have not already performed such analysis?

Question 8 must be answered with respect to any confidentiality claims pertaining to the enclosed records:

8. For each category of information claimed as confidential, discuss with specificity why release of the information is likely to cause substantial harm to your competitive position. Explain the nature of those harmful effects, why they should be viewed as substantial, and the causal relationship between disclosure and such harmful effects. How could your competitors make use of this information to your detriment?

Questions 9 through 15 must be answered for each type of information that you claimed as confidential:

9. For what period of time do you request that the information be maintained as confidential? If the occurrence of a specific event will eliminate the need for confidentiality, please specify that event.
10. Information submitted to EPA becomes stale over time. Why should the information you claim as confidential be protected for the time period specified in your answer to question number 9?
11. What measures have you taken to protect the information? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose it further? If so, why should it still be considered confidential?
12. Has any governmental body made a determination as to the confidentiality of the information? If so, please attach a copy of the determination.
13. Is the presence of this information disclosed in any publicly available material such as Material Safety Data Sheets, promotional publications, annual reports, articles, etc.? Is there any means by which a member of the public could obtain access to the information?
14. Do you assert that the information is "voluntarily submitted" as defined at 40 CFR § 2.201(i)? If so, explain why, and how disclosure would tend to lessen EPA's ability to obtain similar information in the future.
15. Any other issue you deem relevant.

Please note that you bear the burden of substantiating your confidentiality and trade secret claim(s) pursuant to 40 CFR § 2.208(e). Generalize or conclusory allegations will be given little or no weight in EPA's determination on the confidentiality of information you claim to be CBI.

If you wish to claim any information that you provide in your response to this letter to itself be confidential, you must mark the response "**CONFIDENTIAL**" or with a similar designation, and must bracket all text in the response that you so claim. Information so designated will be disclosed by the EPA only to the extent allowed by, and by means of the procedures set forth in, 40 C.F.R. Part 2, Subpart B. If you fail to claim the information provided in your response as confidential, it may be made available to the public without further notice to you.

Be advised that information described by Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") section 10(d)(1)(A), (B), and (C) is not automatically entitled to confidential treatment. Disclosure of such information would only be prohibited, by FIFRA section (b), if the information is eligible for confidential treatment as described by 40 CFR 2.208.

Your reply can be mailed to the following address:

Or your reply can be delivered to my attention at the following address:

Your comments must be postmarked or hand-delivered by the 15th working day after your receipt of this letter. If you intend to submit timely comments, please notify by phone: [TELEPHONE], by email: [EMAIL ADDRESS], or by mail at the address above. Failure to submit timely comments will be regarded as a waiver of your confidentiality claim and EPA will release the information. You may request an extension of the 15-day deadline. Except in extraordinary circumstances, no extension will be granted without the permission of the requester.

Should you have any questions in this matter, please contact: [CONTACT PERSON].

Sincerely,

[SIGNATORY AND TITLE]

Enclosures

OMB 2020-0003  
Approval expires

**By Certified U.S. Mail; Return Receipt Requested**

**MAY CONTAIN CONFIDENTIAL BUSINESS INFORMATION**

*[Technical Contact Name, title, Company, and Address]*

Re: Notice of Review and Request for Substantiation of Confidential Business Information  
Claim(s)

Document Type:

Document Identifying Number:

Date of Submission:

Type of claim(s) to be reviewed:     ☐ specific chemical identity  
   ☐ all other CBI claims

Dear *[Addressee]*:

Under the Toxic Substance Control Act (TSCA) most confidential business information (CBI) claims for chemical identity and at least 25% of other CBI claims are subject to a review and final determination. TSCA section 14(g). 15 U.S.C. § 2613(g).

This letter is to notify you that the U.S. Environmental Protection Agency (EPA) Office of General Counsel will be making a final confidentiality determination concerning information you have claimed as CBI, as identified above. All non-exempt CBI claims must be substantiated.

If you feel that some or all of the information checked above is entitled to confidential treatment, you must substantiate as described below with specific reference to those portions of the information you consider confidential.

Note that TSCA section 14(c)(2) generally exempts certain information types from the requirement to substantiate. 15 U.S.C. § 2613(c)(2). *See* EPA webpage [INSERT WEBPAGE] for more guidance on information exempt from substantiation. To the extent that you believe the information that you have claimed as CBI is one of these exempt information types, you may make this assertion in your response by identifying the specific section 14(c)(2) exemption, in

lieu of substantiating the CBI claim for that information. If the Agency disagrees with this assertion, you may be asked to provide additional information to support your claim.

### **Substantiating a CBI Claim.**

There are two different sets of substantiation questions for CBI claims: (I) questions for all CBI claims in the submission; and (II) questions for chemical identity CBI claims. Please use the appropriate question set. In some instances, your TSCA submission may contain both types of CBI claims or a CBI claim may require completing both sets of substantiation questions. For example, if you assert a CBI claim to protect a chemical substance's identity, then you must answer both question sets. EPA has identified the appropriate question set(s) via the checkboxes at the top of this letter. In some instances, for example TSCA section 8(a) Chemical Data Reporting (CDR) Rule submissions, you may have already provided up-front substantiations for some of the CBI claims. If you have already substantiated your CBI claim at the time of submission, please refer to or preferably physically attach your substantiation to your response to this letter.

Note also that the providing of incorrect information in this substantiation request may be a failure to comply with TSCA, specifically 15 U.S.C. § 2614.

### **I. REQUIRED FOR ALL CBI CLAIMS.**

**If you are asserting ANY information in the submission as CBI, please answer the following questions.**

In supporting your CBI claim(s), please be specific by page, paragraph, sentence, or by data element when identifying and substantiating the information subject to your claim. Where your claim, as originally made or as modified by your response to this letter, does not include all information on a page, please attach a copy of each such page with brackets around the text that you claim to be CBI.

In some cases, it may be appropriate to group the information into a class of information rather than responding to each item claimed as CBI. See EPA webpage [INSERT WEBPAGE] for suggested approaches to providing substantiations of materials grouped. For any information that is not specifically identified as subject to a confidentiality claim and substantiated as such in your response to this letter, it shall be determined that you have waived your CBI claim, pursuant to 40 C.F.R. § 2.205(d).

For each item or class of information that you continue to claim as CBI, please answer the following questions, giving as much detail as possible. Your substantiation response to these questions will be used by the EPA to determine whether the information has been shown to be entitled to confidential treatment:

- A. Do you believe that any of the information claimed as CBI is exempt from substantiation pursuant to TSCA section 14(c)(2)<sup>1</sup>? Yes/No.

If you answered yes, please identify the information, provide the specific exemption and answer no further questions related to that information.

If you answered no, please respond to the questions below.

- B. Will disclosure of the information likely result in substantial harm to your business competitive position? Yes/No.

If you answered yes, please describe with specificity the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public. In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitor's access to your customers.

- C. To the extent you have disclosed information to others (both internally and externally), what precautions has your business taken? Please identify any measures or internal controls your business has taken to protect the information claimed as confidential.

1. Non-disclosure agreement required prior to access. Yes/No
2. Access is limited to individuals with a need-to-know. Yes/No
3. Information is physically secured (e.g. locked in room or cabinet) or electronically secured (encrypted, password protected, etc.). Yes/No
4. Other internal control measure(s). If so, please explain.

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<sup>1</sup> TSCA Section 14(c)(2) states:

**(2) Information generally not subject to substantiation requirements**

Subject to subsection (f), the following information shall not be subject to substantiation requirements under paragraph (3):

(A) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

(B) Marketing and sales information.

(C) Information identifying a supplier or customer.

(D) In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents.

(E) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article.

(F) Specific production or import volumes of the manufacturer or processor.

(G) Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify the specific chemical substance, if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under section 2604 of this title.

- D. Does the information claimed as confidential appear in any public documents, including (but not limited to) safety data sheet, advertising or promotional material, professional or trade publication, or any other media or publications available to the general public? Yes/No.

If you answered yes, please explain why the information should nonetheless be treated as confidential.

- E. Does the information claimed to be CBI contain (a) trade secret(s)<sup>2</sup> ? Yes/No

If yes, please explain the reason for your belief. Please attach copies of those pages containing such information with brackets around the text that you claim to be (a) trade secret(s).

- F. If you assert a claim of confidentiality that is less than 10 years (see TSCA section 14(e)(1)(B)), then please indicate the number of years (between 1-10 years) or specific date of which the claim is withdrawn.<sup>3</sup>

- G. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? Yes/No.

If yes, please explain the outcome of that determination and provide EPA with a copy of the previous confidentiality determination or any information that will assist the Agency in identifying the prior determination.

## II. REQUIRED FOR ONLY CHEMICAL IDENTITY CBI CLAIMS.

**If you are claiming a specific chemical identity as CBI, please answer the additional following questions.** If you are not substantiating a chemical identity CBI claim, then you do not need to respond to the questions below.

- A. Is the chemical substance on the confidential portion of the TSCA Inventory? Yes/No.

- B. Commerce:

1. Has the chemical substance (or mixture) been offered for commercial distribution? Yes/No.

2. Is the chemical substance known to be in U.S. commerce? Yes/No.

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<sup>2</sup> “Trade secret” is defined as “a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort.” Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983).

<sup>3</sup> Information with withdrawn CBI claims will be made available to the public without further notice.

If you answered yes, please explain why the information should nonetheless be treated as confidential.

C. Disclosure of the specific chemical name would release:

1. Confidential process information. Yes/No.
2. Confidential portion of a mixture information. Yes/No.

If you answered yes to either question, please explain.

### **Asserting a CBI claim in your substantiation response.**

Businesses may claim their substantiation response as CBI. Information claimed as confidential should be clearly marked by bracketing, circling, or underlining. All pages containing such information must also be stamped "CONFIDENTIAL BUSINESS INFORMATION" or with similar designation in order to assert a confidentiality claim. Care should be taken to ensure that these markings do not obscure the text.

If you claim your substantiation response as CBI, you must include the following statement in the submission.

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.

I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

- (i) My company has taken reasonable measures to protect the confidentiality of the information;
- (ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
- (iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and
- (iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

### **Timely Responses and Postal Requirements**

Your substantiation response must be postmarked or hand delivered to this office **by the 15th working day after your receipt of this letter.** While it is anticipated that there will be a means



for sending these to the Agency electronically in the future, at this point substantiations should be sent via US Mail or courier.

**Filings should be directed to the below address.**

TSCA Confidential Business Information Center (7407M)  
WJC East; Room 6428; Attn: TSCA CBI Substantiations  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460-0001

**Courier Deliveries:**

U.S. EPA  
Office of Pollution Prevention and Toxics  
Confidential Business Information Center (CBIC)  
Attn: TSCA CBI Substantiations  
1201 Constitution Avenue, NW  
WJC East; Room 6428  
Washington, DC 20004-3302  
(202) 564-8930

You may seek an extension of time to submit your substantiation response to this office, but the request must be made before the end of the 15-day period. Requests for an extension may be directed to Ms. Quoc Nguyen, Office of General Counsel, [Nguyen.Quoc@epa.gov](mailto:Nguyen.Quoc@epa.gov).

**Failure to timely submit your substantiation response will be regarded as a waiver of your confidentiality claim or claims, and the EPA may release the information.**

Should you have any questions concerning this matter, please contact Mr. Scott Sherlock, (202) 564-8257 and [Sherlock.Scott@epa.gov](mailto:Sherlock.Scott@epa.gov); or Ms. Jessica Barkas, (202) 250-8880 and [Barkas.Jessica@epa.gov](mailto:Barkas.Jessica@epa.gov).

Sincerely,

[Signature and Title; Office Name and Address]



UNITED STATES DEPARTMENT *of* JUSTICE

# Advanced Procedural Requirements



At the most basic level, an agency's FOIA process can be conceptualized as receipt, search, review, and response.

Within these very broad steps are many procedural requirements that must be fulfilled in order to comply with the FOIA.



This lecture will provide an in-depth discussion of some of the more complex areas of the FOIA's procedural requirements, including:

- Search
- Review
- Active Track Management
- "Unusual Circumstances"
- Fees



## Search: Reasonableness

An agency must conduct a reasonable search, one "*reasonably calculated to uncover all relevant documents.*"

Recent case law has refined an agency's obligations when conducting a search in response to a FOIA request.



## **Competitive Enter. Inst. v. Office of Sci. and Tech. Policy, (D.C. Cir. 2016)**

Request for records if maintained on a nonofficial email account.

Court holds that "[i]f the agency head controls what would otherwise be an agency record, then it is still an agency record and still must be searched or produced."



## Competitive Enter. Inst. v. Office of Sci. and Tech. Policy

"If a department head can deprive the citizens of their right to know what his department is up to by the simple expedient of maintaining his departmental emails on an account in another domain, that purpose is hardly served."



Despite the ruling in *Competitive Enter. Inst. v. Office of Sci. and Tech. Policy*, courts have found there are still limitations on search obligations.





## **Hamdan v. DOJ, (9th Cir. 2015)**

Court holds "[p]laintiffs have made no showing that by the close of the FBI's search, leads had emerged suggesting a need to search other databases."

Overall, the court finds that "[p]laintiffs were entitled to a reasonable search for records, not a perfect one."



## **Wright v. Admin. for Children and Families**, (D.D.C. Oct. 11, 2016)

"[A]n agency is only required to search record systems 'likely' to yield responsive documents."

Court finds that "plaintiff's purely speculative contentions cannot render the agency's search inadequate."



## **Search: Form & Format**

An agency must *make reasonable efforts to search for records in multiple formats, including any electronic formats.*

The definition of form and format have expanded somewhat, especially if the search or review of records in different formats is not burdensome.



**Public.Resource.org v. IRS**, (N.D. Cal.  
2015)

Request for Modernized E-file (MeF) format  
of Form 990s for nine tax exempt  
organizations.

IRS argued that the \$6,200 needed to develop  
protocols and train staff to redact information  
in these forms meant that they were not  
"readily producible."



## **Public.Resource.org v. IRS**

Court found no evidence, including the one-time expense of \$6,200, that the general business of the IRS would be significantly burdened by fulfilling the request.

"[T]hat the IRS will have to develop new protocols and train staff to respond to [plaintiff's] request does not somehow excuse its need to comply with E-FOIA."



## Search and Retrieval or Record Creation

The FOIA does not require agencies to create records in response to FOIA requests.

However, there is a difference between "creating a record" and compiling records stored in an electronic database.



## **National Sec. Counselors v. CIA,** **(D.D.C. 2012)**

Court discusses "the distinction between searching and either performing research or creating records," which the court admits "remains somewhat muddled."



## **National Sec. Counselors v. CIA**

"[I]n response to a FOIA request for 'aggregate data,' . . . an agency need not create a new database or reorganize its method or archiving data, but if the agency already stores records in an electronic database, searching that database does not involve the creation of a new record"





## “Burdensome Search” or “Not Reasonably Described”

Two distinct, possibly conflated concepts that impact searches.

Agencies need to ensure that they conduct a search for records that reasonably describes the records sought even if the search itself is complex.



## **Shapiro v. CIA, (D.D.C. 2016)**

Request for records concerning Nelson Mandela.

Court finds that, "[r]egardless of how onerous it might be to locate them, there can be no dispute about which items are being requested—records in the CIA's possession that 'mention[ ]' Nelson Mandela or his three listed aliases."



## Shapiro v. CIA

"FOIA's reasonable-description requirement does not doom requests that precisely describe the records sought, even if compliance might overwhelm an agency's response team."



## Review: Non-Responsive Material

Prior to 2016, many district courts approved the practice of redacting or “scoping out” non-responsive material.

However, the issue was recently addressed by D.C. Circuit Court in *American Immigration Lawyers Association v. EOIR*, 830 F.3d 667 (D.C. Cir. 2016).



# **American Immigration Lawyers** **Association v. EOIR** (D.C. Cir. 2016)

The FOIA “does not provide for . . .  
redacting non-exempt information within  
responsive records.”



# **American Immigration Lawyers** **Association v. EOIR** (D.C. Cir. 2016)

As declared by the court, “once an agency identifies a record it deems responsive to a FOIA request, the statute compels disclosure of the responsive record—i.e., as a unit—except insofar as the agency may redact information falling within a statutory exemption.”



# **American Immigration Lawyers** **Association v. EOIR** (D.C. Cir. 2016)

As a result, it will be important for agencies to carefully define what they consider to be the “records” responsive to a request.

OIP has issued guidance on defining a record as well as some practical considerations.



## **Guidance on Defining a Record**

*Look to the Privacy Act's Definition of "Record"*

- Each "item, collection, or grouping of information" on the topic of the request can be considered a distinct "record."
- Thus, a "record" could be the entire document, a single page of a multipage document, or an individual paragraph of a document.





## Practical Considerations

To the extent agencies identify multi-subject documents that they divide into discrete “records” for purposes of responding to a particular FOIA request, they must ensure that they take that into account anytime they refer to the volume of “records” responsive to the request.



## **Practical Considerations**

When marking records for disclosure, the agency should mark the distinct records clearly.

When possible, the agency should release headings, bullets or other textual content that illustrates that the document contains multiple subjects.



## Active Track Management

FOIA statute permits multitrack processing of requests, allowing agencies to group requests into queues **"based on the amount of work or time (or both) involved in processing requests."**

To realize the benefits and efficiencies of multitrack processing, agencies should actively manage requests in these tracks.



## Active Track Management

Processing of an individual request should be the deciding factor in determining if a request is "simple" or "complex."

This is important because the initial track determination can change once processing begins based on the **amount of work** or **time required** or **both** to process.



## **Active Track Management**

*Example:* Request seeks ten years' worth of correspondence between agency and a member of Congress.

A search of the electronic correspondence system finds no records, and the agency is able to respond to the requester within a short amount of time.



## **Active Track Management**

Active management of processing tracks helps ensure that requests needing similar time to process are being grouped together, allowing quicker processing of "simple track" requests.

Agencies can work with requesters to tailor requests to fit in the "simple" track as a way of reducing processing time.



## "Unusual Circumstances"

If "unusual circumstances" exist, an agency may extend the 20 working day time limit for response by 10 additional days by providing written notice to the requester.



## "Unusual Circumstances"

- Search in separate offices.
- Examine voluminous records.
- Consultations with another agency or two or more agency components.





## "Unusual Circumstances"

Searching in separate offices and consultations can be fairly straight forward to understand.

Examining a voluminous amount of material can be more difficult as few cases exist that directly rule on a certain number being "voluminous."



**Davis v. DHS**, (E.D.N.Y. Nov. 20, 2013)

Held that unusual circumstances existed when request was for "sixteen thousand pages and fifteen CDs of potentially responsive records."

**Munger, Tolles & Olson LLP ex rel.  
American Management Services v.  
Dept. of Army**, (C.D. Cal. 2014)

Suggested that approximately 400 pages of records was not voluminous.



**Tereshchuk v. BOP, (D.D.C. 2014)**

"FOIA anticipates that requests for records may be so voluminous as to require an agency to carry an unusual workload" and "[w]hen an agency is asked to [process a voluminous request] it may have extra time to comply"

**Sierra Club v. Dept. of Interior, (D.D.C. 2004)**

Held that "onerous request" involving "hundreds of pages" constituted unusual circumstances



## "Unusual Circumstances"

General framework from these cases is that voluminous requests are ones which ask an agency to carry out an unusual workload.

Needing to examine hundreds of pages may not qualify, mid-hundreds might, and thousands of pages usually will.



## Fee Determinations

Over the last two years, there have been statutory developments, as well as amendments and new case law that may impact how agencies make determinations on FOIA fee decisions.



## FOIA Improvement Act of 2016

Prior to the *FOIA Improvement Act of 2016*, there was a prohibition on the charging of certain fees when the FOIA's time limits where not met.

The exceptions to this prohibition were broad and permitted the assessment of fees when "unusual" or "exceptional" circumstances applied.



## FOIA Improvement Act of 2016

With the amendments, these exceptions have been narrowed.

Now, when an agency fails to comply with any time limit for responding to a request, there are limitations on its ability to assess certain fees unless an exception is met.



# FOIA Improvement Act of 2016

## "Exceptional Circumstances":

- If court determines that "exceptional circumstances exist[,]" the agency's failure to comply with a time limit "shall be excused for the length of time provided by the court order." (1)





# FOIA Improvement Act of 2016

## "Unusual Circumstances":

- When "unusual circumstances" apply, and the agency has "provided a timely written notice to the requester[,]" the delay is "excused for an additional 10 days." (2)



## FOIA Improvement Act of 2016

"If the agency fails to comply with the extended time limit[,]" it may not charge search fees (or for requesters with preferred fee status, may not charge duplication fees), unless the last exception is met.



# **FOIA Improvement Act of 2016**

Agencies may still charge fees if:

- Timely written notice of unusual circumstances is provided to the requester;
- "more than 5,000 pages are necessary to respond to the request," and
- The agency discussed with the requester via written mail, electronic mail, or telephone (or made not less than 3 good-faith attempts to do so) how the requester could effectively limit the scope of the request. (3)



# **FOIA Improvement Act of 2016**

OIP has issued guidance to assist agencies in understanding the prohibitions on assessing certain fees when the FOIA's time limits are not met and the exceptions to these limitations.

Guidance is available at:

[https://www.justice.gov/oip/oip-guidance/  
prohibition\\_on\\_assessing\\_certain\\_fees\\_when\\_fo  
ia\\_time\\_limits\\_not\\_met](https://www.justice.gov/oip/oip-guidance/prohibition_on_assessing_certain_fees_when_foia_time_limits_not_met)



## Fee Determinations

In *Cause of Action v. FTC*, (D.C. Cir. 2015) the court clarified the definition of "Representative of the News Media" for fee purposes.



## Cause of Action v. FTC

"[A]ny person or entity that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience."

"In this clause, the term 'news' means information that is about current events or that would be of current interest to the public."



## Cause of Action v. FTC

Key Elements for Determination - Look at requester's **overall activities**:

1. Gathering information of potential interest to segment of the public.
2. Using editorial skills to turn raw material into distinct work.
3. Disseminating that work to an audience.



## Cause of Action v. FTC

With "gathering information," the court ruled that this fee category is focused:

- "on the nature of the requester, not its request."
- A case-by-case approach is not necessary.





## Cause of Action v. FTC

For "editorial skills," under this decision, a requester can create a "distinct work" based solely on FOIA-released documents.

*Example:* Substantive press release about documents or editorial comments can be "distinct work."



## Cause of Action v. FTC

For dissemination of a work to an audience:

- Size of audience does not matter.
- Not necessary to have track record if there are firm plans.
- Fact-based determination based on past record, current operations, and future plans.



## Fee Determinations

In *Sack v. DOD*, (D.C. Cir. 2016) the definition of "Educational Institutions" for fee purposes was expanded.



## Sack v. DOD

"[T]o qualify . . . [t]he requester – whether teacher or student – must seek the information in connection with his or her role at the educational institution."



## Fee Determinations

When taken together, the decisions in *Cause of Action v. FTC* and *Sack v. DOD* impact how agencies will make fee category determinations.



## Case Citations

*Competitive Enter. Inst. v. Office of Sci. and Tech. Policy*, 827 F.3d 145 (D.C. Cir. 2016)

*Hamdan v. DOJ*, 797 F.3d 759 (9th Cir. 2015)

*Wright v. Admin. for Children and Families*, No. 15-218, 2016 WL 5922293 (D.D.C. Oct. 11, 2016)

*Public.Resource.org v. IRS*, 78 F. Supp. 3d 1262 (N.D. Cal. 2015)



## Case Citations

*Nat'l Sec. Counselors v. CIA*, 898 F. Supp. 2d 233 (D.D.C. 2012)

*Shapiro v. CIA*, 170 F. Supp. 3d 147 (D.D.C. 2016)

*American Immigration Lawyers Association v. EOIR*, 830 F.3d 667 (D.C. Cir. 2016)

*Davis v. DHS*, No. 11-203, 2013 WL 6145749, at \*2 (E.D.N.Y. Nov. 20, 2013)



## Case Citations

*Munger, Tolles & Olson LLP ex rel. Am. Mgmt Servs. v. Dept. of Army*, 58 F. Supp. 3d 1050, 1055 (C.D. Cal. 2014)

*Tereshchuk v. BOP*, 67 F. Supp. 3d 441, 455 (D.D.C. 2014)

*Sierra Club v. Dept. of Interior*, 384 F. Supp. 2d 1 (D.D.C. 2004)

*Cause of Action v. FTC*, 799 F.3d 1108 (D.C. Cir. 2015)

*Sack v. DOD*, 823 F.3d 687 (D.C. Cir. 2016)





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**Questions?**